

## **REMARKS / ARGUMENTS**

### **Disposition of the Claims**

The present response is intended to be a full and complete response to the Office Action mailed May 28, 2009. Claims 43, 44, 46 to 49 and 54 to 56, as amended, and newly added claims 57 to 59, are pending in the present application. Applicants respectfully request continued examination and allowance of all pending claims.

### **Amendments To The Claims**

Claim 43 has been amended to indicate that the addiction is to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances and that the medicament consists of a mixture of 20% to 32% by volume of xenon and from 20% to 40% by volume of nitrous oxide with the remainder being selected from oxygen, an oxygen/nitrogen mixture and air. Claims 44, 47 and 54 have been amended for consistency with the claims from which they depend. Claims 48 and 56 have been amended to indicate that the addiction is to amphetamines. Claim 55 has been amended to indicate that the addiction is to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances and that the medicament consists of from 10% to 20% by volume of xenon, from 45% to 50% of nitrous oxide with the remainder being selected from the group consisting of oxygen, an oxygen/nitrogen mixture and air. Newly added claim 57 depends from claim 55 and indicates that the addiction is to amphetamines. Newly added claims 58 to 59 depend from claim 55 and further limit the medicament. Applicants respectfully request entry of said amendments.

### **First 35 U.S.C. § 112, First Paragraph, Rejection**

The Examiner rejects claims 43, 44, 46 to 49 and 54 to 56 under 35 U.S.C. § 112, first paragraph, on the basis that the specification, while being enabling for treatment of drug addiction, does not reasonably provide enablement for prevention and treatment of any and all drug additions. This rejection is respectfully traversed with regard to claims 43, 44, 46 to 49, 54 to 56, as amended, and newly added claims 57 to 59.

Applicants note that claims 43 and 55 have been amended to indicate that the addition being prevented/treated is addition to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances. Accordingly, Applicants maintain that claims 43 and 55 are now enabled. The remaining claims each depend directly or indirectly upon claim 43 or claim 55, as amended, and therefore are also enabled. Newly added claims 57 to 59 depend from claim 55, as amended, and are therefore also enabled.

In view of the above, Applicants respectfully request that the rejection of claims 43, 44, 46 to 49 and 54 to 56, as amended, and newly added claims 57 to 59 be withdrawn.

#### **Second 35 U.S.C. § 112, Second Paragraph, Rejection**

The Examiner rejects claims 48 and 56 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner notes that the claims recite: “amphetamines and derivatives thereof” and indicates that derivatives is indefinite because it is unclear how far one can theoretically make derivatized amphetamines and still retain function and therefore the structure of is unknown. Accordingly, the Examiner suggests removing the term “derivatives”.

Applicants note that claims 48 and 56 have been amended to indicate that the addition is to amphetamines. Accordingly, in view of these amendments, Applicants maintain that the rejection is rendered moot. Applicants further note that claims 43 and 55 have been amended to indicate that the addition is to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances. Applicants note that the language “and derivatives thereof” is not included in these amendments of claims 43 and 55. Accordingly, Applicants maintain that claims 43 and 55, as amended, are also not indefinite.

Applicants respectfully request that this rejection under 35 U.S.C. § 112, second paragraph, be withdrawn in view of these amendments.

### **First 35 U.S.C. § 103 Rejection**

The Examiner retains the rejection of claims 43, 44, 46 to 49, and 54 to 56 under 35 U.S.C. § 103(a) as being unpatentable over Lecourt et al., U.S. Publication No. 2002/0033174 (hereinafter “Lecourt”) in view of Petzelt et al., WO 2000/53192 (hereinafter “Petzelt”) and Jevtovic-Todorovic et al. “Nitrous Oxide (laughing gas) Is An NMDA Antagonist, Neuroprotectant And Neurotoxin” (hereinafter “Jevtovic-Todorovic”) and Brooks, U.S. Patent No. 5,846,556 (hereinafter “Brooks”). This rejection is respectfully traversed with regard to claims 43, 44, 46 to 49 and 54 to 56, as amended, and newly added claims 57 to 59.

Applicants respectfully disagree with the position of the Examiner and maintain that the present invention is not obvious in view of the references cited by the Examiner since one of ordinary skill in the art, considering the references cited by the Examiner, would not be led to the specific formulation claimed by Applicants for the prevention or treatment of addiction to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances.

The first independent claim of the present invention comprises a gaseous inhalable medicament for the prevention or treatment of addiction to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances. The medicament utilized consists of from 20% to 32% by volume of xenon and from 20% to 40% by volume of nitrous oxide, with the remainder of the mixture being selected from the group consisting of oxygen, an oxygen/nitrogen mixture or air. The second independent claim is also directed to the prevention or treatment of addiction to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances using a medicament consisting of from 10% to 20% by volume of xenon and from 45% to 50% by volume of nitrous oxide, with the remainder of the mixture being selected from the group consisting of oxygen, an oxygen/nitrogen mixture or air. In other words, in each of these embodiments, the only components of the mixture are xenon, nitrous oxide and a “remainder” gas selected from oxygen, an oxygen/nitrogen mixture or air.

The primary reference cited, Lecourt, discloses an inhalable aerosol medicament for the treatment or prevention of pain. Lecourt uses at least one gas in combination with at least

one active product for the treatment of pain. The active product is chosen from among paracetamol, acetylsalicylic acid, arylcarboxylic acid, corticosteroids, mineralosteroids, non-steroidal anti-inflammatory drugs and their derivatives, codeine and its derivatives, morphine and morphine mimetics. The “at least one gas” is selected from a laundry list of possible gases.

The objective of Lecourt is the delivery of an active product (from the list set out by Lecourt) aided by the use of one or more gases from the laundry list. As noted in paragraph [0021] of Lecourt, the solution to the prior art problems for administering the active product is through the use of inhalation to administer the active substances to the patient. Lecourt does not disclose that the active product is optional (that the medicament can comprise simply a combination of gases).

The initial burden of presenting a prima facie case of obviousness lies with the Examiner. See, *Ex Parte DuBois*, Appeal No. 2009-001593, slip op. at 3 (BPAI June 2009)(quoting *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992)). In order to establish a prima facie case of obviousness, the Examiner must show that each and every limitation of the claim is described or suggested by the prior art or would have been obvious based on the knowledge of those of ordinary skill in the art. *Id.*, slip op. at 3 – 4, (quoting *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988)). “When considering claims for obviousness, ‘the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill.’” See, *Ex parte Von Rheinbaben et al.*, Appeal No. 2009-000837, slip op. at 13 (BPAI June 2009)(quoting *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986)). The United States Supreme Court in *KSR* noted that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.*, slip op. at 11 (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)). The Supreme Court in *KSR* further noted that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does ... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is

already known.” Id. Accordingly, “[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” Id. (quoting *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) quoting *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965)).

In reply to Applicants’ previous response to the previous Office Action, the Examiner indicates that Applicants’ assertion that Lecourt uses at least one gas in combination with at least one active product whereas in the instant invention the medicament is xenon and nitrous oxide is not persuasive because the instant claims use open language which can allow for additional active agents. Applicants note that the instant claims have been limited to include closed language which provides that the medicament is a specific range of xenon in combination with a specific range of nitrous oxide with the remainder of the mixture being oxygen, an oxygen/nitrogen mixture or air. Accordingly, Applicants now maintain that in view of this closed language, that Lecourt is even less relevant as Lecourt requires the addition of at least one active product for the treatment of pain—a product which is not included in the formulation of Applicants.

Furthermore, Lecourt teaches that the combinations suggested by Lecourt are for the treatment of pain—not the treatment of drug addiction. Lecourt does not in any manner address prevention or treatment of addiction to specific types of drugs as in the present invention. Applicants maintain that this is because the composition is Lecourt, which differs from that of the present invention, is not considered to be useful for the treatment or prevention of addiction. While the Examiner states that the treatment of drug addiction is intrinsic to the composition since such undisclosed use is inherent in the referenced composition, Applicants respectfully disagree. Such a conclusion presupposes that the person that is being treated for pain is also addicted to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances. In addition, there is nothing in the art cited by the Examiner which would lead one skilled in the art to eliminate the active product of Lecourt in an effort to then provide a formulation that is useful for treating or preventing

addiction. By virtue of the fact that Lecourt calls this an “active” product, this implies that the product is required in the formulation.

Finally, one skilled in the art, considering the references cited by the Examiner, would not be led to believe that if the active ingredient of Lecourt were eliminated and a combination of nitrous oxide, xenon and a remainder gas as in the present invention (without the inclusion of an active product such as those disclosed in Lecourt) were used instead it would be possible to treat or prevent addiction to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances. Applicants instead maintain that one skilled in the art, considering Lecourt in view of the secondary references, would instead be led to believe that various combinations of nitrous oxide and xenon can only be sufficient for use as carrier gases for an active product such as those claimed in Lecourt for the treatment of pain.

In view of the above, Applicants maintain that claims 43, 44, 46 to 49 and 54 to 56, as amended, and newly added claims 57 to 59, are patentable over Lecourt in view of Petzelt, Jevtovic-Todorovic and Brooks. Accordingly, Applicants respectfully request the withdrawal of the rejection of these claims under 35 U.S.C. § 103(a).

#### **Second 35 U.S.C. § 103 Rejection**

The Examiner rejects Claims 47 to 49 and 54 to 56 under 35 U.S.C. § 103(a) as being unpatentable over Mondain-Monval, U.S. Patent No. 4,820,258 (hereinafter “Mondain-Monval”). This rejection is respectfully traversed with regard to claims 47 to 49 and 54 to 56, as amended, and newly added claims 57 to 59 which depend from claim 55.

First Applicants note that claim 54 depends indirectly from claim 43. Accordingly, in view of the fact that claim 54 does not depend from claim 55, Applicants request that the Examiner clarify if this claim was intended to be included in this rejection.

With regard to the rejection, Applicants respectfully disagree with the position of the Examiner and maintain that the present invention is not obvious in view of the references cited by the Examiner since one of ordinary skill in the art, considering the references cited by the Examiner, would not be led to the specific formulation claimed by Applicants for the

prevention or treatment of addiction to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances.

Mondain-Monval discloses a method for delivering radiation to target tissue of a patient undergoing cancer radiotherapy by first administering a gaseous mixture containing at least about 50% by volume of nitrous oxide (preferably from 50% to 80% by volume) and at least about 20% by volume of oxygen. In one embodiment of Mondain-Monval, it is noted that this formulation can comprise a ternary mixture in which the complement to 100 by volume is an inert gas selected from nitrogen, argon, krypton, xenon and helium. According to the Examiner, the reference does not teach that the composition can be used in treating drug addiction to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances but that the undisclosed use is inherent in the reference composition. Applicants respectfully disagree.

As noted above, “[w]hen considering claims for obviousness, ‘the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill.’” See, *Ex parte Von Rheinbaben et al.*, Appeal No. 2009-000837, slip op. at 13 (BPAI June 2009)(quoting *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986)). Accordingly, “[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *Id.* (quoting *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) quoting *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965)).

Applicants maintain that one skilled in the art, considering Mondain-Monval would consider the reference as a whole and in considering the reference as a whole would not overlook the criticalities of Mondain-Monval—primarily being that while delivered in stages, the actual teachings of Mondain-Monval provide the administering of the combination of xenon, nitrous oxide and an inert gas as a precursor to the delivery of radiation. In other words, the combination is a precursor to the administering of radiation (that the actual teaching is for administering the formulation with radiation). In addition, the “inert” gas is

selected from a group which based on the teachings of Mondain-Monval appears to give equal weight to the various gases listed.

More specifically, the teachings of Mondain-Monval provide that the gaseous mixture is administered followed by the radiation. In other words, what is being administered is the gaseous mixture in combination with the radiation. Accordingly, Applicants maintain that one skilled in the art considering Mondain-Monval would not administer the combination of the specific amounts of xenon, nitrous oxide and an inert gas without administering the corresponding radiation. Therefore, to say that the administering of the combination of xenon, nitrous oxide and an inert gas is inherent presupposes that one skilled in the art would eliminate the radiation portion of the treatment. Applicants maintain that this is not the case.

In addition, Applicants maintain that Mondain-Monval fails to disclose the criticality of the xenon and instead lists this gas as an “inert” gas to the composition. In other words, this gas is simply a filler to achieve the desired ratios set out in Mondain-Monval. One skilled in the art considering Mondain-Monval would be led to believe that one gas would work as well as any other gas.

Applicants further maintain that claim 59 is even more removed from the teachings of Mondain-Monval since claim 59 provides that the remainder is selected from an oxygen/nitrogen mixture and air which Mondain-Monval do not disclose as being options for consideration.

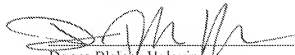
In view of the above, Applicants maintain that claims 47 to 49 and 54 to 56, as amended, and newly added claims 57 to 59 are patentable over Mondain-Monval.



CONCLUSION

In view of the above, Applicants maintain that the pending claims are now in condition for allowance. Early notice to this effect is earnestly solicited. Should the Examiner believe a telephone call would expedite the prosecution of the present application, the Examiner is invited to call the undersigned attorney at the number listed below.

Respectfully submitted,

  
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Date: August 28, 2009

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